REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which are believed to place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 24, 25, 30-32, 38 and 43-49 are pending in this application. Claims 24, 25, 30-32 and 38 are amended; claims 43-49 are added. Support for the amended claims is found throughout the specification. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

The amendment filed November 6, 2003 was objected to under 35 U.S.C. §132 because it allegedly introduced new matter into the disclosure. While the Applicants disagree that the added material is new matter, it has been deleted in order to advance prosecution.

II. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH ARE OVERCOME

Written Description

Claims 24-26, 30-32 and 34-42 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The recitation involving 16 consecutive nucleotides has been removed from the claims, thereby obviating the rejection.

Claims 37-42 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The recitation involving 20-24 consecutive nucleotides has been removed from the claims, thereby obviating the rejection.

Enablement

Claims 24-26, 30-32 and 34-42 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

The language now recited in claims 24, 30 and 43 has been chosen to emphasize that the PCR assay is performed with MS-B2 specific primer pairs. As discussed on page 16, line 21, to page 17, line 6, of the specification, "specific primers" means "primers which specifically recognize the elite event", not other sequences in the genome. As has been indicated before on the record, the principle of a PCR assay is that a fragment is amplified using two primers that hybridize to DNA, whereby the DNA sequence between those two primers is amplified. It is the combination of the two primers and the DNA fragment generated by the combination of those primers that makes the PCR assay specific. The two members of the claimed primer pairs are, respectively, directed against the plant DNA flanking the foreign DNA of elite event MS-B2 (specified in the claims as "nucleotides 1-234 of SEQ ID NO:8" for the 5' flank and "nucleotides 194-416 of SEQ ID NO:10" for the 3' flank) and the foreign DNA of elite event MS-B2 (now specified in the claims as "nucleotides 235-415 of SEQ ID NO:8" for the 5' flank and "nucleotides 1-194 of SEQ ID NO:10" for the 3' flank). Consequently, each of the two claimed primer pairs will amplify a DNA fragment that is specific for elite event MS-B2.

To more clearly define that the claimed primer pairs are specific for elite event MS-B2 and that the generated DNA fragment is specific for elite event MS-B2, the claims were further amended to incorporate that, when the PCR assay using the claimed primer pairs is performed on genomic DNA from plant material which contains the elite event, an MS-B2 specific DNA fragment is generated; and that, when the PCR assay using the claimed primer pairs is performed on genomic DNA from plant material which does not contain the elite event, it will not generate said MS-B2 specific DNA fragment. (The latter can be determined simply by including the positive and the wild type control in the PCR assay, as was done, *e.g.*, in Example 5.2. Examples 5.2.2 and 5.2.7 define positive and wild type controls. Figure 5, lanes 1 and 6, shows the positive and wild type controls, respectively, as described in Example 5.2.8.)

Hence, if the members of the claimed primer pairs would unexpectedly bind non-specifically to regions in the genome other than the plant DNA flanking the foreign DNA of elite event MS-B2 and the foreign DNA of elite event MS-B2, respectively, as hypothesized by the Examiner, *e.g.*, because they comprise repetitive sequences, these primers would prove not to be

useful after performing the assay on a wild-type, positive and, optionally, a negative control sample. (Example 5.2.7. explains how the PCR results can be validated.) Further, even if a non-specific fragment were generated, which would require that both members of the used primer pair would hybridize to the plant DNA in such a way that a DNA fragment can be generated, which clearly will not be likely to occur, this fragment would be recognized as non-specific.

The Examiner notes on page 5 of the Office Action that 20-base long primers comprised in bases 1-234 of SEQ ID NO:8 or bases 194-416 of SEQ ID NO:10 or SEQ ID NO:1, or the complement thereof, would encompass approximately 12600 20-base long primers with exact complementarity and multitudes more primers of other lengths and/or with mismatches. Initially, it should be noted that the claims now recite bases 235-415 of SEQ ID NO:8 and bases 1-193 of SEQ ID NO:10, instead of SEQ ID NO:1, to refer to the foreign DNA of MS-B2. Moreover, as the Examiner is aware, claims directed to "a DNA molecule encoding the protein of SEQ ID NO:X" are frequently granted. Nevertheless, such claims can cover many more DNA sequences than are disclosed, especially for large proteins. See, for example, claim 1 of U.S. Patent No. 6,677,442, copy enclosed, which claims "An isolated nucleic acid molecule comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:9". SEQ ID NO:9 represents a protein of 1251 amino acids and, due to the degeneracy of the genetic code, each amino acid can be encoded by up to 4 different codons. Consequently, this claim encompasses a very large genus of DNA sequences, the vast majority of which are not disclosed in the specification. However, a person skilled in the art can, based on their knowledge of the genetic code, envision and prepare each and every DNA sequence encompassed by such claims, just as s/he can envision and prepare, based on the specified sequences disclosed in the instant application, each and every primer encompassed by the pending claims.

In view of the amendments and arguments submitted herein, reconsideration and withdrawal of the §112, first paragraph, rejections are requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, 2ND PARAGRAPH ARE OVERCOME

Claims 24-26, 30-32 and 34-42 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejections are traversed.

The Office Action alleges that it is not clear how PCR is used. Claims 24 and 43 recite "performing a polymerase chain reaction on a genomic DNA sample", and describe the primer pair to be used. PCR is a standard assay and its use is well established. There is, therefore, no

indefiniteness in its recitation in the claims, even without reciting each and every step of the reaction. The skilled artisan knows what is meant by "performing a polymerase chain reaction" and can do so based on his knowledge of the art and the disclosure in the application. In addition, as indicated in Example 5.2 of the specification, when the "MS-B2 Elite Event Polymerase Chain Reaction Identification Protocol" is used, "a test run, with all appropriate controls, has to be performed before attempting to screen unknowns. The presented protocol might require optimization for components that may differ between labs (template DNA preparation, Taq DNA polymerase, quality of the primers, dNTP's, thermocycler, *etc.*)". Thus, the recitation of specific reaction conditions would be unduly limiting, as these conditions could vary slightly depending on several factors. These variations are anticipated by those of skill in the art, within whose abilities it lies to make necessary adjustments.

To that end, enclosed are several patents that recite PCR without reciting reaction steps or conditions:

- U.S. Patent No. 6,713,259 claims methods and kits for detecting corn event MON810 DNA using PCR assays (*e.g.*, in claim 4) and Southern blot assays (*e.g.*, in claim 7) without reciting specific reaction conditions. It should be noted that the description of the primers in the granted claims of this patent is similar to previously recited descriptions of the primers in the current case.
- U.S. Patent No. 6,733,974 claims methods and kits for detecting the presence of the nptII/35S genetic construct using PCR assays (*e.g.*, in claim 8) and Southern blot assays (*e.g.*, in claim 10) without reciting specific reaction conditions. The method claims recite specific primer sequences, while the kit claims, *e.g.*, claim 5, recite primers of about 11 or more contiguous nucleotides of SEQ ID NO:1 and 2, or a complements thereof.
- U.S. Patent No. 6,395,485 claims methods and kits for detecting elite event GAT-ZM1 using PCR assays (*e.g.*, in claim 2) and Southern blot assays (*e.g.*, in claim 11) without reciting specific reaction conditions. It should be noted that the description of the primers in the granted claims of this patent is similar to the presently recited description of the primers in the current case.

On page 8 of the Office Action, the Examiner suggests adding language to the claims that specifies the conclusion reached, depending on whether a fragment is produced or not. This has been done.

The Office Action goes on to allege that "specific primer" is indefinite. A "specific primer" does not differ from a primer comprising the recited sequence; however, "specific primer" is ascribed a certain meaning by its use in the specification, and it is not believed that that meaning is unclear.

The remaining rejections are obviated by amendments removing the offending words or phrases. Accordingly, reconsideration and withdrawal of the rejections under §112, second paragraph, are requested.

CONCLUSION

Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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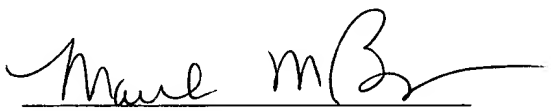
By: 

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